K102937

5. 510(k) Summary as required by section 807.92(c)

5.1. FDA Contact Person

DEC 27 2010

Victor Bowers

VP Medical Affairs

Phone (262) 642-2765
Cell (262) 581-5161
Fax (262) 642-2745
Email vbowers@cytophil.com

5.2. 510(k) Owner

William G. Hubbard Ph.D.

President & CEO

Cytophil, Inc.

2485 Corporate Circle, Suite 2

East Troy, WI 53120

Phone (262)642-2765

Cell (262) 757-3081

Fax (262) 624-2745

Email bhubbard@cytophil.com

5.3. 510(k) Preparer/submitter

Victor Bowers

VP Medical Affairs

Cytophil, Inc.

2485 Corporate Circle, Suite 2

East Troy, WI 53120

Phone (262)642-2765

Cell (262) 581-5161

Fax (262) 624-2745

Email vbowers@cyotphil.com

[807.92(a)(1)]

5.4. Device Name[per 807.92(a)(2)]

Trade (proprietary) name :	Osteophil B-TCP
Common name:	Synthetic Bone Graft Material
Classification name:	Resorbable Calcium Salt Bone Void Filler

5.5. Legally Marketed device to which your firm is claiming equivalence [807.92(a)(3)]

Equivalent legally marketed Device title	510(k) number
CAMCERAM TCP	K050357

5.6. Description of the device [807.92(a)(4)]

Osteophil B-TCP is a porous calcium phosphate resorbable bone void filler for the repair of bony defects. The product consists of beta-Tricalcium Phosphate and is about 80% porous. The product is provided sterile and is available in granules 1-4 mm[1].

Osteophil B-TCP has a multidirectional interconnected porosity structure, similar to that of human cancellous bone. Osteophil B-TCP slowly resorbs during the remodeling and bone defect repair process and is progressively replaced with bone and soft tissues. The progressive resorption of Osteophil B-TCP resorbable bone filler is intended to prevent premature resorption.

5.7. Intended use of the device [807.92(a)(5)]

Osteophil B-TCP is a resorbable bone void filler intended to fill bony void or gaps of the extremities, posterolateral spine, and pelvis that are caused by trauma or surgery and are not intrinsic to the stability of the bony structure.

This intended use of the device is identical to and, therefore, equivalent to predicate K050357 - CAMCERAM TCP.

5.8. Summary of the technological characteristics of your device compared to the predicate device. [807.92(a)(6)]

Osteophil B-TCP has the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate device, K050357 - CAMCERAM TCP. Following is a summary of the technological characteristics of Osteophil B-TCP in comparison to those of the predicate device, K050357 - CAMCERAM TCP.

Characteristic	Substantially Equivalent?	Impact on Safety & Performance
Device		
Design	YES	None
Material Characterization	YES	None
Biocompatibility	YES	None
Sterilization	YES	None
Physical Properties		
Identification of Device Material	YES	None
Additives	NA	NA
Ca/Phosphorus Ratio	YES	None

[1] 1-4 mm equals 1000 – 4000 um

Elemental Analysis	YES	None
X-Ray Diffraction Patterns	YES	None
Dimensional Specifications	YES	None
Physical Form of the Device	YES	None
Device Density	YES	None
Device Mass	YES	None
Device Volume	YES	None
Device Porosity • Total Porous Volume • Pore Diameter • Interconnectedness	YES	None
pH Testing	YES	None
Dissolution Testing (mg/L/hr)	YES	None
Energy Source	NA	NA

Osteophil B-TCP has substantially equivalent critical specifications as CAMCERAM TCP - K050357.

Osteophil B-TCP has substantially equivalent technical characteristics as the predicate K050357 - CAMCERAM TCP. The chemical and physical characteristics are compared in section 11.2. These characteristics include the following:

- Chemical Composition by XRD spectra
  - Phases present
  - Ca:P ratio
- Physical Properties
  - Physical Form
  - Dimensional Specifications
  - Porosity
  - Bulk density
- Performance Testing
  - pH
  - In vitro dissolution rate
  - Animal testing to determine bone in-growth and resorption of the implant over time

The characteristics were evaluated by performing testing using standardized laboratory test methods. The test results demonstrate the substantial equivalence of the technical characteristics of Osteophil B-TCP to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Cytophil, Inc.
% Victor M. Bowers
2485 Corporate Circle, Suite 2
East Troy, WI 53120

DEC 27 2010

Re: K102937
Trade/Device Name: Osteophil B-TCP
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: September 28, 2010
Received: October 4, 2010

Dear Mr. Bowers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indication for Use Statement

DEC 2 7 2010

4.1. 510(k) Number

(If known): K 102937

4.2. Device Name

Osteophil B-TCP

4.3. Indications for Use

Osteophil B-TCP is a resorbable bone void filler intended to fill bony void or gaps of the extremities, posterolateral spine, and pelvis that are caused by trauma or surgery and are not intrinsic to the stability of the bony structure.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over-the-Counter Use _____

[Per 21 CFR 801.109]

(Division Sign-Off)

Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K102937